



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
-----------------	-------------	----------------------	---------------------

09/060,872 04/15/98 ESTELL

D GC527

HM12/0526
GENENCOR INTERNATIONAL INCORPORATED
925 PAGE MILL ROAD
PALO ALTO CA 94304-1013

EXAMINER

SAUNDERS, D

ART UNIT	PAPER NUMBER
----------	--------------

1644

DATE MAILED: 05/26/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

060,572

Applicant(s)

ESTELL et al

Examiner

SAUNDERS

Group Art Unit

1644

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 2/2/99
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-16 is/are pending in the application.
- Of the above claim(s) 1-12, 15-16 is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 13-14 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____
 - ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☒ Notice of Reference(s) Cited, PTO-892
- ☒ Notice of Draftsperson's Patent Drawing Review, PTO-948 (SUBSTITUTE) ☐ Other _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152

Office Action Summary

Art Unit: 1644

Applicant's election without traverse of Group IV (claims 13-14) in Paper No. 6 is acknowledged.

The application contain sequences that fall within the definitions of nucleic acid or amino acid or amino acid sequences set forth in 37 CFR 1.821(a) (1) and 1.821 (a) (2). Some of the sequences recited in the specification (e.g. page 8) have SEQ ID NOS; however other sequences have no identifiers (e.g. the E06 sequence at page 28). It is further noted that Figs. 6A-6C present 116 peptide sequences with no identifiers. See MPEP 2422.02 regarding sequences presented in Figures. Applicant is required to provide a SEQ ID No. For every sequence presented in the specification and figures. Applicant must provide a paper sequence listing as a part of the specification and must provide the sequence on a diskette.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

Claim 13 is rejected under 35 U.S.C. 102(b) as being anticipated by or in the alternative under 35 USC 103(2) as obvious over King (5,593,877) .

King teaches identification of T-cell epitopic sites in phospholipase or hyaluronidase allergens found in insect venom. See col.20, lines 23-44. Immunomodulatory peptides

Art Unit: 1644

containing the identified T-cell epitopes can be therapeutically administered to patients. See col.22, lines 7-13 and 29-40. See col.19, line 33-col.20, line 57 for teachings of how to identify immunomodulatory peptides. The peptides can be modified by amino acid substitutions (col.18, lines 10-31) or by chemical treatments (col.19, lines 5-19). Peptides that induce T-cell Anergy can be identified (col. 20, lines 38-44). Applicant's claim language of "modifying said protein" is interpreted broadly as encompassing fragmentation of the allergenic protein to merely its T-cell epitope(s), with or without any of the further modifying treatments such that the peptide fragment induces T-cell anergy or non-responsiveness in lieu of anergy. Thus the reference properly anticipates.

Claims 13-14 are rejected under 35 U.S.C. 102(e) as being anticipated by Garman et al (5,820,862).

Garman et al show the identification and therapeutic use of T-cell epitope sequences from house dust mites in a manner similar to King, cited supra. T-cell epitopes can be modified by substitution so as to induce T-cell anergy while inducing reduced or no proliferative response. The manner by which such T-cell epitope sequences would be modified, as disclosed at column 20, lines 27-44, is considered to be one which would preserve the major tertiary structural features associated with critical binding of the epitope to T-cell receptors. This the disclosure of Garman et al is consistent with embodiment © of instant claim 14.

The following reference is cited as of interest. Garrity et al (5,585,250) show methods of reducing the immunogenicity of B-cell epitopes.

Art Unit: 1644

Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. Saunders whose telephone number is (703) 308-3976. The examiner can normally be reached on M-F from 8:15 to 4:45.

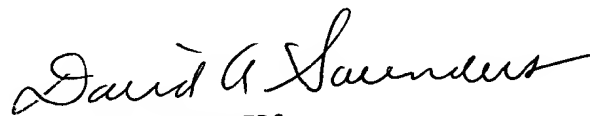
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, C. Chan, can be reached on (703) 308-3973. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Saunders/sg

May 12, 1999

April 26, 1999



DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT 182

1644